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מתקן לשמירה על לחץ לאחר עצירת דם (בעברית) (Hebrew)

DEVICE FOR MAINTAINING POST-HEMOSTASIS PRESSURE (באנגלית) (English)

hereby apply for a patent to be granted to me in respect thereof. מבקש בזאת כי ינתן לי עליה פטנט

*בקשת חלוקה - Application of Division	*בקשת פטנט מוסף - Application for Patent Addition	*דרישה דין קדימה Priority Claim		
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מתקן לשמירה על לחץ לאחר עצירת דם

DEVICE FOR MAINTAINING POST-HEMOSTASIS PRESSURE

DEVICE FOR MAINTAINING POST-HEMOSTASIS PRESSURE

Field of the Invention

The present invention relates to a device for maintaining pressure on a blood vessel puncture site that has been sealed following a percutaneous medical procedure.

Background of the Invention

During several surgical procedures, for example in treatment of vascular diseases, it is a common practice to invade a blood vessel and introduce a treating or diagnostic device, e.g. balloons or various types of stents to operate on walls of the arteries, plaque removing devices, observation and flow diagnostic instruments, etc.

During such procedures, a blood vessel is punctured so as to allow introduction of an instrument therethrough, which is maneuvered thereinafter to the required site of operation. This is carried out in practice by introducing a guide sheath, through which the instrument can then be easily maneuvered to the site of interest.

Bleeding occurs upon completion of the procedure and removal of the guide sheath. Bleeding may result in hematoma or, in severe cases, to malfunction of critical organs and even death. Such bleeding is generally stopped by the

application of digital pressure by a health care professional who applies pressure for a sufficiently long period of time until hemostasis takes place to spontaneously seal the puncture and stop the bleeding. Hemostasis may be augmented by the use of a pressure-applying dressing, adhesive-elastic bandages and/or sandbags.

Following inducement of hemostasis- hereinafter referred to as "post-hemostasis"- pressure needs to be continually applied onto the puncture site. When the blood vessel is the femoral artery, pressure may be maintained for as long as 2-6 hours. At times, recurrent bleeding, particularly if the patient is not in rest, or other complications, such as hematoma and formation of a pseudoaneurysm, may occur. Due to the placement of bandages or the like directly over a puncture site in order to maintain pressure thereat, such complications are liable not to be noticeable at the puncture site, and irreversible bodily damage may result.

It is an object of the present invention to provide a post-hemostasis pressure maintaining device which is configured such that a puncture site is visible, in order to prevent the occurrence of complications.

It is an object of the present invention to provide a post-hemostasis pressure maintaining device by which a puncture site may be monitored.

It is an additional object of the present invention to provide a device by which the total time for applying pre-hemostasis and post-hemostasis pressure onto a blood vessel puncture site may be reduced, relative to the prior art.

Other objects and advantages of the invention will become apparent as the description proceeds.

Summary of the Invention

The present invention provides a post-hemostasis pressure maintaining device, which comprises a tissue-confining device having two parallel longitudinally bars which extend between a proximal end and a distal end; and means for retaining said tissue-confining device in compressing contact with tissue in the vicinity of a sealed puncture site of a blood vessel.

The term "tissue-confining device," as referred to herein, denotes a device with an open area bounded by its frame, which is externally placed over, or in contact with, a limb of a patient and above a sealed puncture site of the blood vessel, and is so configured that following the application of an axial force to said tissue-confining device it entraps, within said open area, and compresses, tissue in the vicinity of the punctured blood vessel. A tissue-confining device generally comprises two parallel, longitudinally extending bars, interconnected at or adjacent their respective proximal and/or distal ends by at least one arcuate connecting member. The depth to which the tissue in the vicinity of the sealed puncture site is compressed depends on the magnitude of said axial force and the

rigidity of said tissue. The tissue-confining device is therefore fixated with respect to said blood vessel.

Prior to introduction of a guide sheath into a blood vessel, tissue is punctured by a needle held at an inclination with respect to a horizontal plane ranging from 45-60°. After the skin and then the blood vessel are punctured, a wound canal is formed between the skin puncture site and the blood vessel puncture site, which are separated due to the inclination of the tissue-puncturing needle. During hemostasis, the skin puncture site and the blood vessel puncture site are both sealed. Application of axial pressure onto a tissue-confining device reduces the angle of the wound canal, causing surrounding tissue to apply a pressure onto the sealed blood puncture site so as to maintain hemostasis. Blood flow through the blood vessel is not constricted by the tissue-confining device or by the retaining means as tissue in the vicinity of the sealed puncture site is compressed.

The tissue-confining device preferably has an open area bounded by spaced apart longitudinally extending bars and at least one connecting bar, the sealed puncture site being visible via said open area.

In one aspect, axial pressure is applied onto the tissue-confining device by means of an adjustable artery clamp apparatus, said tissue-confining device being detachable from said artery clamp apparatus.

The term "artery clamp apparatus," as referred to herein, denotes an apparatus and a structure that supports said apparatus, which allows for the compressing of tissue in the vicinity of a sealed puncture site of a blood vessel, particularly an artery, by means of a tissue-confining device. An "adjustable artery clamp apparatus" denotes an artery clamp apparatus that may be displaced in a controllable fashion, e.g. wherein the structure is axially and transversally displaceable relative to the sealed puncture site.

As referred to herein, "axial" means a direction from the artery clamp apparatus to a blood vessel, "longitudinal" means a direction parallel to the axis of a blood vessel and "transversal" means a direction perpendicular to the longitudinal direction. "Proximal" means towards the upstream side of blood flow and "distal" means towards the downstream side of blood flow, relative to a sealed puncture site.

Preferably, the retaining means comprises proximal and distal strap assemblies which are attached to the proximal and distal ends, respectively, of the tissue-confining device.

The term "strap," as referred to herein, denotes an element which is engageable under tension with tissue external to the tissue-confining device and is preferably, but not necessarily, rectangular. A strap may be an elastic bandage, an adhesive bandage, a belt, cloth, or a combination thereof.

Each strap assembly preferably comprises means for angularly displacing and/or for axially displacing at least one strap.

In one embodiment of the invention, the angularly displacing means comprises an axially extending member in fixed relationship with the tissue-confining device by means of a connecting element detachably connected to the tissue-confining device; and an element affixed to said at least one strap which is rotatably attached to said axially extending member and supported by an abutment plate provided with the axially extending member. The axially extending member is preferably a bolt which is threadedly engageable with an internally threaded bolt support connected to, or integral with, the connecting element.

In one aspect, the pressure by which the at least one strap adheres to tissue is adjustable upon lowering or raising the abutment plate by means of the bolt, with the at least one strap remaining at substantially the same angle with respect to the bolt support.

In another aspect, the axially displaceable member is axially displaceable by hydraulic or pneumatic means.

In another embodiment of the invention, each strap assembly comprises a U-shaped element having two mutually parallel, longitudinally extending legs, a connector attached to one of said legs, and an L-shaped element connected at one

end to said connector and detachably connected at the other end thereof to a longitudinally extending bar of the tissue-confining device. A strap is securable to a corresponding leg of the U-shaped element and is wrapped around the limb in which the sealed puncture site is disposed.

The present invention is also directed to a post-pseudoaneurysm closure maintaining device, comprising a tissue-confining device having two parallel longitudinally bars which extend between a proximal end and a distal end; and means for retaining said tissue-confining device in compressing contact with tissue in the vicinity of a closed pseudoaneurysm neck.

Brief Description of the Drawings

In the drawings:

- Fig. 1 is a perspective view of a post-hemostasis pressure maintaining device, according to one embodiment of the invention;
- Fig. 2 is a perspective view of the device of Fig. 1 in attachment to an artery clamp apparatus;
- Figs. 3A-C are perspective views of three configurations of a tissue-confining device, respectively;
- Figs. 4 and 5 are perspective views of the device of Fig. 1, illustrating the attachment of a pair of strap assemblies to the tissue-confining device;
- Fig. 6 is a perspective view of the device of Fig. 1, illustrating the detachment of the artery clamp apparatus from the tissue-confining device;

- Figs. 7 and 8 are perspective views of another embodiment of a post-hemostasis pressure maintaining device;
- Fig. 9 is a perspective view of the device of Fig. 7, illustrating a strap assembly employing more than two angularly displaceable straps; and
- Fig. 10 is a perspective view of the device of Fig. 7, illustrating the attachment of a pair of strap assemblies to the tissue-confining device.

Detailed Description of Preferred Embodiments

Fig. 1 illustrates a post-hemostasis pressure maintaining device according to one embodiment of the present invention, generally designated as numeral 10, comprising a tissue-confining device generally designated as numeral 20 and a pair of strap assemblies 30A and 30B.

Following the piercing of a blood vessel so that a guide sheath, for example, may be introduced therein during a surgical procedure and the subsequent sealing of the puncture site, tissue-confining device 20 is held adjacent to the sealed puncture site, such that the blood vessel is interposed between, and substantially parallel to, longitudinally extending bars 22. After axial pressure is applied onto tissue-confining device 20 in order to achieve hemostasis, for example by means of artery clamp apparatus 40 (Fig. 2) described in Published International Application WO 03/099350 by the same Applicant, such that the tissue-confining device is fixated with respect to the blood vessel, straps 33A-D are tensed, fixed in position and adhesively attached to the corresponding limb of the patient, so that the tissue-confining device may be retained in compressing contact with

tissue in the vicinity of a sealed puncture site. Tissue-confining device 20 is then detached from artery clamp apparatus 40 (Fig. 6), while pressure continues to be applied by the tissue-confining device and the straps to tissue in the vicinity of the sealed puncture site, and particularly to the wound canal formed during the surgical procedure, so that hemostasis may be maintained without constriction of the blood vessel.

At times, the puncture site is at a relatively inaccessible location and the straps cannot be affixed to tissue while being transversally disposed. The present invention provides means for angularly displacing the straps, so that they may be affixed to tissue at a more accessible location.

In one embodiment of the invention, each strap assembly 30A and 30B comprises a U-shaped element 32 having two mutually parallel, longitudinally extending legs 37, connector 34 attached to one leg 37 and L-shaped element 36 connected at one end to connector 34 and detachably connected at the other end thereof to tissue-confining device 20 via a suitably shaped aperture 25 formed in bar 22 (Fig. 3A) of the tissue-confining device. Each strap 33A-D is secured to a corresponding leg of U-shaped element 32 by any suitable means well known to those skilled in the art, and is adhesively affixed to tissue outwardly from the tissue-confining device, when the straps are adhesive. When the straps are elastic bandages, each strap may be connected to the opposed strap of the corresponding strap assembly, after being wrapped around the limb in which the

sealed puncture site is disposed. As shown, straps 33A and 33B are secured to strap assembly 30A and straps 33C and 33D are secured to strap assembly 30B.

U-shaped element 32 is advantageously pivotable with respect to the corresponding connector 34, so that the straps may be angularly displaced. U-shaped element 32 may also be axially displaceable with respect to tissue-confining device 20 by suitable gripping means (not shown) housed within connector 34.

As shown in Fig. 2, artery clamp apparatus 40 for applying axial pressure onto tissue-confining device 20 in order to achieve hemostasis comprises base plate 48, locking device 49, extendible arcuate arms 42 and adapter 45, which is fixedly connected to the arcuate arms and is detachably connected to tissue-confining device 20 by means of rods 41 (Figs. 3A-C and 6), e.g. by a pressure fit. Artery clamp apparatus 40, when used, is positioned such that tissue-confining device 20 is disposed directly above a puncture site. As arcuate arms 42 are extended, tissue-confining device 20 is lowered, compressing the tissue of the patient in the vicinity of the sealed puncture site, until the tissue-confining device is fixated with respect to the blood vessel.

Alternatively, axial pressure may be manually applied onto the tissue-confining device, by the hands of a medical professional, if so desired, such that the tissue in the vicinity of the sealed puncture site will be compressed, until the tissue-confining device is fixated with respect to the blood vessel.

Referring now to Figs. 3A-C, the distance between the two longitudinally extending bars 22 of each tissue-confining device, ranging from 5-80 mm, is selected so that the transversal spacing between a blood vessel, within which a catheter was guided during a recent surgical procedure, and each bar 22 ranges from 0.25-4 cm. With such a transversal spacing, the two bars 22, which are immobilized while being in pressing engagement with tissue and may be supported by a bone in the vicinity of the blood vessel, when the tissue-confining device applies axial pressure to the underlying tissue, the blood vessel is fixated by compressed tissue that is interposed between the blood vessel and each bar 22. Base plate 48 (Fig. 2) placed underneath the limb of the patient further contributes to the stabilization of the tissue-confining device.

In the shown exemplary configurations of a tissue-confining device, each connecting bar 27 which connects the two longitudinally extending bars 22, whether at the distal or proximal end thereof, is provided with a curvature with respect to a vertical plane, such that the connecting bar 27 is elevated above a longitudinally extending bar. This curvature retains mechanical integrity of the tissue-confining device without applying transversal pressure to the blood vessel that would reduce the blood flow therethrough, since the connecting bar is not in contact with the tissue. In Fig. 3A, two connecting bars 27 are employed at the proximal and distal ends, respectively, of tissue-confining device 20A, while in Fig. 3B only one is used, with an opening 28 being formed at the proximal end of tissue-confining device 20B. Opening 28 advantageously allows for the

visualization of the puncture site and for the placement and repositioning of an imaging device, whenever necessary. In Fig. 3C, the distal end of tissue-confining device 20C is provided with two ends 29, which are in a spaced, opposed relation with one another, having a curvature with respect to a vertical plane.

Figs. 4 and 5 illustrate the attachment of strap assemblies 30A and 30B to tissue-confining device 20. The L-shaped elements 36 of the two strap assemblies 30, respectively, are connected by longitudinally extending cross member 38. Cross member 38 is placed inwardly to arms 42, that is between the arms and the tissue-confining device, as shown in Fig. 4, and then lowered, as shown in Fig. 5, until each pin 47, e.g. a spring-biased pin, formed on the bottom of a corresponding L-shaped element 36 is directly above a corresponding aperture 25 (Fig. 3A) formed in bar 22 of the tissue-confining device. Further lowering of cross member 38 results in the engagement of pins 47 with bar 22, as shown in Fig. 1.

The proximal strap assembly 30A and distal strap assembly 30B are secured to each opposed leg 37 of U-shaped element 32, as shown in Fig. 1. Proximal straps 33A and 33B may be adhesively affixed to tissue, or alternatively, may be wrapped around a different periphery of the limb of the patient, tensed, and are then connected together by attachment means 51, such as Velcro. Distal straps 33C and 33D are connected together in a similar fashion. The straps are engagement with tissue in such a way so as to retain the tissue-confining device in compressing contact therewith. If so desired, one strap may be employed,

which is tensed, wrapped around the limb of the patient externally to the tissue-confining device, and affixed to the tissue.

After the straps are properly positioned so as to retain the tissue-confining device in compressing contact with tissue in the vicinity of the sealed puncture site, as described hereinabove, adapter 45 may be detached from tissue-confining device 20, as shown in Fig. 6. Upon retraction of arcuate arms 42, adapter 45 is raised and post-hemostasis pressure maintaining device 10 remains in contact with the limb of the patient. Following detachment of adapter 45 from tissue-confining device 20, the latter continues to be fixated with respect to the punctured blood vessel by means of the tensile force applied by the straps.

Due to the unique configuration of the tissue-confining device, wherein an open area is defined by the area between the longitudinal bars, a physician may clearly view the puncture site via said open area as hemostasis is being maintained. A physician may therefore notice manifestation of a complication during post-hemostasis, such as recurrent bleeding, hematoma and formation of a pseudoaneurysm, therefore preventing irreversible bodily damage.

The open area may also be advantageously utilized for monitoring the sealed puncture site by an imaging device. Since the tissue-confining device is fixated with respect to the blood vessel, an imaging device attached to the tissue-confining device, or being fixedly nested to a seat formed therein, may transmit a stable, substantially clear image of the puncture site. The imaging device may be

an ultrasound device, such as an X-ray imaging device, for providing required data concerning blood flow through the blood vessel.

With employment of a tissue-confining device described hereinabove, such as those illustrated in Figs. 3A-C, the total time for applying pre-hemostasis and post-hemostasis pressure onto a blood vessel puncture site may be considerably reduced, relative to the prior art.

Published International Application WO 03/099350 by the same Applicant, the content of which is incorporated herein by reference, discloses an apparatus for sealing a puncture in a blood vessel. The apparatus comprises a tissue-confining device, as described hereinabove, which is connected to an adjustable artery clamp apparatus for controllably applying pressure, such as by a fluid circuit, onto the blood vessel. The artery clamp apparatus comprises in a preferred embodiment a proximal plunger and a distal plunger positioned upstream and downstream, respectively, to a skin puncture site. The proximal plunger applies sufficient axial pressure to a blood vessel in order to induce partial or total occlusion, and the distal plunger applies axial pressure directly onto the blood vessel puncture site. During partial occlusion, the diastole and systole temporarily disappear and the blood flow velocity at an arterial puncture site is reduced. Improved coagulation occurs in the absence of vibration or pulsation in the arterial walls, as the blood platelets accumulate easier at the puncture site, thereby reducing the hemostasis time.

Following inducement of hemostasis, the plungers (not shown), which are longitudinally displaceable by means of a corresponding slider 56 (Fig. 2) of rectangular cross section that is slidingly received, by a dovetail arrangement, within a corresponding groove formed within adapter 45 (Fig. 2), may be longitudinally displaced and removed from adapter 45. As the tissue-confining device remains in compressing contact with tissue in the vicinity of the sealed puncture site, the strap assemblies are attached to the tissue-confining device as described hereinabove, straps are wrapped around the corresponding limb of the patient, the artery clamp apparatus is detached from the tissue-confining device, and pressure application to tissue in the vicinity of the sealed puncture site is maintained during post-hemostasis. By employing the same tissue-confining device for both hemostasis and post-hemostasis, valuable time of health professionals is more efficiently utilized.

Figs. 7-10 illustrate another and more preferred embodiment of the invention wherein the strap assembly comprises means for angularly displacing the straps. Each strap assembly 60 comprises connecting element 62 detachably connected to tissue-confining device 20, internally threaded rectangular bolt support 65 integrally formed with, or otherwise fixedly attached to, connecting element 62 in cantilevered fashion, bolt 66 which is threadedly engaged with bolt support 65 and formed with circular abutment plate 69 and head 70, and rectangular strap unifier 72 formed with bore 73. Connecting element 62 has a vertical leg 63 and a horizontal portion 64, and is accordingly arranged so that abutment plate 65 is above and outside of tissue-confining device 20. Straps 75A and 75B, or a single

strap if so desired, are affixed to unifier 72 and then adhesively attached to tissue. The straps may be provided with two-sided adhesion, so that one side of the straps may adhere to unifier 72 and the other side of the straps may adhere to tissue in the vicinity of the tissue-confining device. After unifier 72 is lowered on top of abutment plate 69, with head 70 protruding from bore 73, straps 75A and 75B may be angularly displaced with respect to bolt support 65. The pair of straps supported by the abutment plate 69 thereof, are angularly displaceable, so that the straps may be affixed to tissue at a more accessible location. The pressure by which the straps adhere to tissue may be adjusted by lowering or raising bolt 66, while the straps remain at the same angle with respect to bolt support 65.

It will be appreciated that unifier 72 may be rotatably attached to any other suitable axially extending member which is in fixed relationship with tissue-confining device 20. Hydraulic or pneumatic means may be employed to axially displace the axially extending member, in order to adjust the pressure by which the straps adhere to tissue.

As shown in Fig. 9, each strap assembly 60 may comprise more than one unifier. In the illustrated example, two unifiers are employed, with unifier 77A being affixed to straps 78A and 78B and unifier 77B being affixed to straps 78C and 78D. Straps 77A-C are of sufficient length to be adhesively attachable to tissue outwardly of tissue-confining device 20. Strap 77D has a shortened length, and is used to facilitate affixing to unifier 77B. Unifiers 77A and 77B are both

supported by abutment plate 69 (Fig. 8) after being rotatably attached to head 70, and are disposed at different angular dispositions with respect to horizontal portion 64 of the connecting element.

Two connecting elements 62 are connected by longitudinally extending cross member 78. After tissue-confining device 20 is in compressing contact with the tissue in the vicinity of a sealed puncture site of a blood vessel, the two connecting elements 62 and cross member 78 spanning therebetween are lowered, as shown in Fig. 10, until each pin 47 formed on the bottom of a connecting element 62 is directly above a corresponding aperture 25 (Fig. 3A) formed in bar 22 of the tissue-confining device. Further lowering of cross member 78 results in the engagement of pins 47 with bar 22. The connecting elements may be lowered onto the tissue-confining device before straps are placed in supporting relation with each bolt support 65, as shown. Alternatively, each bolt 66 may be threadedly engaged with the corresponding bolt support 65 and unifier 73 may be placed in supporting relation with the corresponding abutment plate 69 before the connecting elements are lowered onto the tissue-confining device.

The device of the present invention is also suitable for a post-pseudoaneurysm-closure maintaining device. As described in Published International Application WO 03/099350 by the same Applicant, application of an axial force by a proximal plunger proximally to a puncture site and by a distal plunger on the path of blood communication between the artery and the hematoma (commonly referred to as the pseudoaneurysm neck) induces absorption of pseudoaneurysm into an

adjacent blood vessel. The proximal and distal plungers (not shown) are longitudinally displaceable by means of a corresponding slider 56 (Fig. 2) of rectangular cross section that is slidingly received, by a dovetail arrangement, within a corresponding groove formed within adapter 45 (Fig. 2). Supplementary axial pressure applied to the pseudoaneurysm neck may be provided by a longitudinally extending bar of the tissue-confining device.

Following closure of the pseudoaneurysm, the plungers may be longitudinally displaced and removed from the adapter. As the tissue-confining device remains in compressing contact with the pseudoaneurysm neck, the strap assemblies are attached to the tissue-confining device as described hereinabove, straps are engageable with the corresponding limb of the patient, the artery clamp apparatus, if used, is detached from the tissue-confining device, and pressure application to the pseudoaneurysm neck is maintained following closure of the pseudoaneurysm. By employing the same tissue-confining device for both pseudoaneurysm treatment and maintaining post-pseudoaneurysm-closure, valuable time of health professionals is more efficiently utilized.

While some embodiments of the invention have been described by way of illustration, it will be apparent that the invention can be carried into practice with many modifications, variations and adaptations, and with the use of numerous equivalents or alternative solutions that are within the scope of persons skilled in the art, without departing from the spirit of the invention or exceeding the scope of the claims.

CLAIMS

1. A post-hemostasis pressure maintaining device, comprising a tissue-confining device having two parallel longitudinally bars which extend between a proximal end and a distal end; and means for retaining said tissue-confining device in compressing contact with tissue in the vicinity of a sealed puncture site of a blood vessel.

2. Device according to claim 1, wherein the tissue-confining device has an open area bounded by spaced apart longitudinally extending bars and at least one connecting bar, the sealed puncture site being visible via said open area.

3. Device according to claim 1, wherein the retaining means comprises proximal and distal strap assemblies which are attached to the proximal and distal ends, respectively, of the tissue-confining device.

4. Device according to claim 3, wherein each strap assembly comprises means for angularly displacing at least one strap.

5. Device according to claim 3, wherein each strap assembly comprises means for axially displacing at least one strap.

6. Device according to claim 4, wherein the angularly displacing means comprises an axially extending member in fixed relationship with the tissue-confining device by means of a connecting element detachably connected to the tissue-

confining device; and an element affixed to said at least one strap which is rotatably attached to said axially extending member and supported by an abutment plate provided with the axially extending member.

7. Device according to claim 6, wherein the axially extending member is a bolt which is threadedly engageable with an internally threaded bolt support connected to, or integral with, the connecting element.

8. Device according to claim 7, wherein the pressure by which the at least one strap adheres to tissue is adjustable upon lowering or raising the abutment plate by means of the bolt, with the at least one strap remaining at substantially the same angle with respect to the bolt support.

9. Device according to claim 6, wherein the axially displaceable member is axially displaceable by hydraulic or pneumatic means.

10. Device according to claim 3, wherein each strap assembly comprises a U-shaped element having two mutually parallel, longitudinally extending legs; a connector attached to one of said legs; and an L-shaped element connected at one end to said connector and detachably connected at the other end thereof to the longitudinally extending bar.

11. Device according to claim 10, wherein a strap is securable to a corresponding leg of the U-shaped element.

12. Device according to claim 6 or 10, wherein a pair of straps is attachable to a corresponding strap assembly, each strap being wrapped around a different periphery of the limb and connected together by an attachment means.

13. Device according to any of claims 1 to 12, wherein axial pressure is applied onto the tissue-confining device by means of an adjustable artery clamp apparatus, said tissue-confining device being detachable from said artery clamp apparatus.

14. A post-pseudoaneurysm closure maintaining device, comprising a tissue-confining device having two parallel longitudinally bars which extend between a proximal end and a distal end; and means for retaining said tissue-confining device in compressing contact with tissue in the vicinity of a closed pseudoaneurysm neck.

15. Post-hemostasis pressure maintaining device, substantially as described and illustrated.

16. Post-pseudoaneurysm closure maintaining device, substantially as described and illustrated.

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LUZZATTO & LUZZATTO
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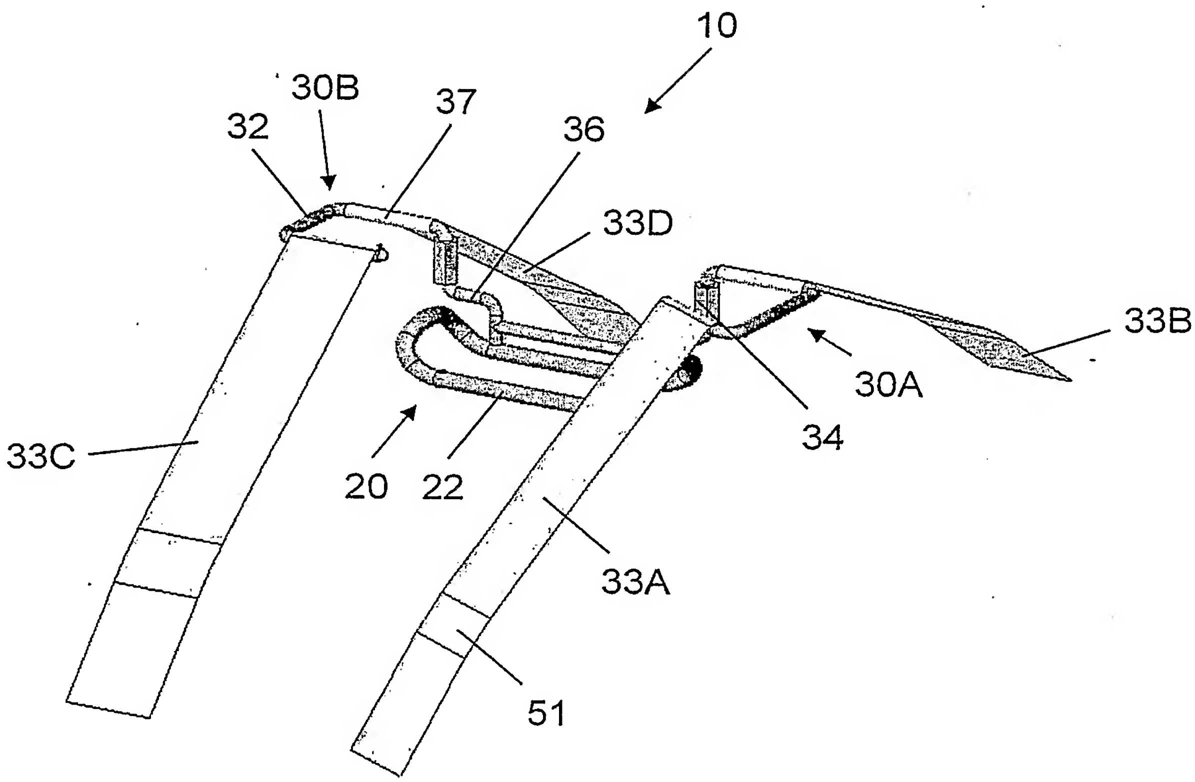

Fig. 1

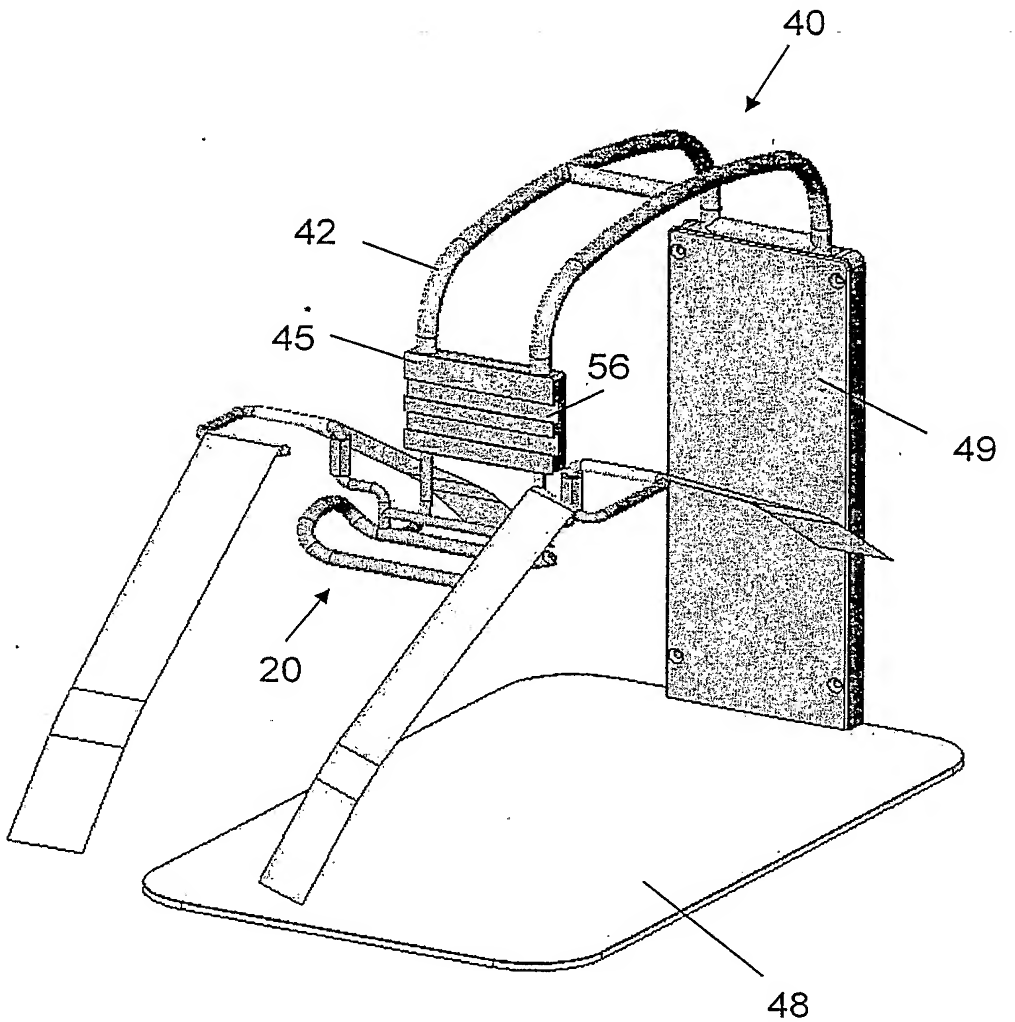

Fig. 2

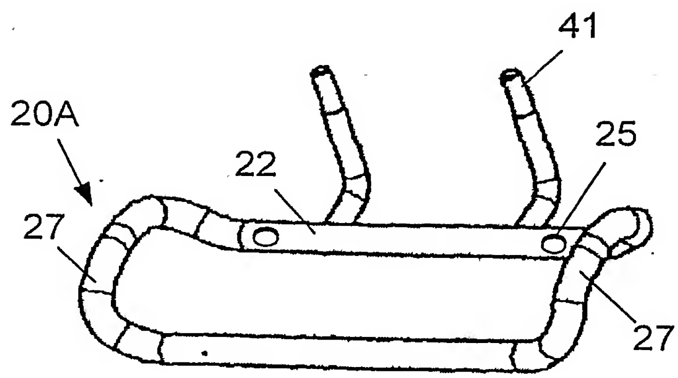

Fig. 3A

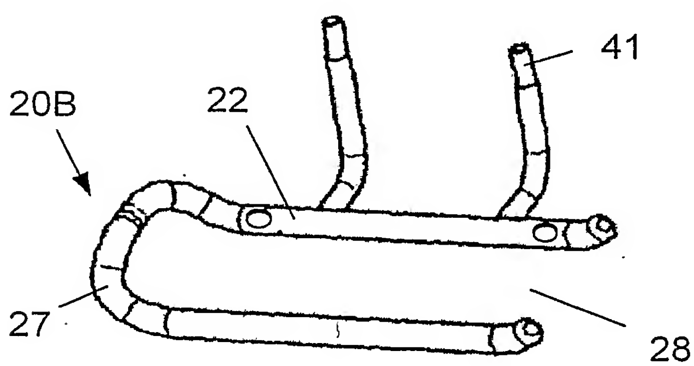

Fig. 3B

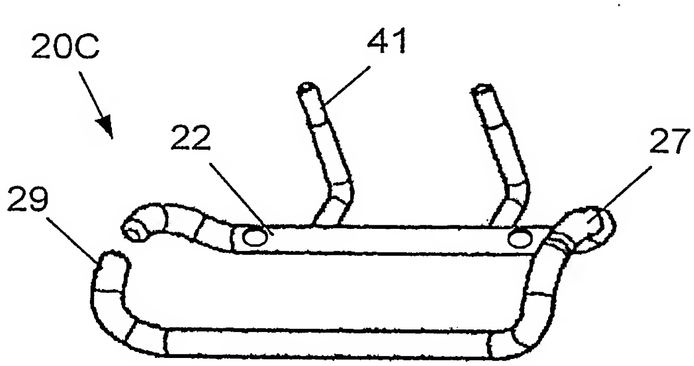

Fig. 3C

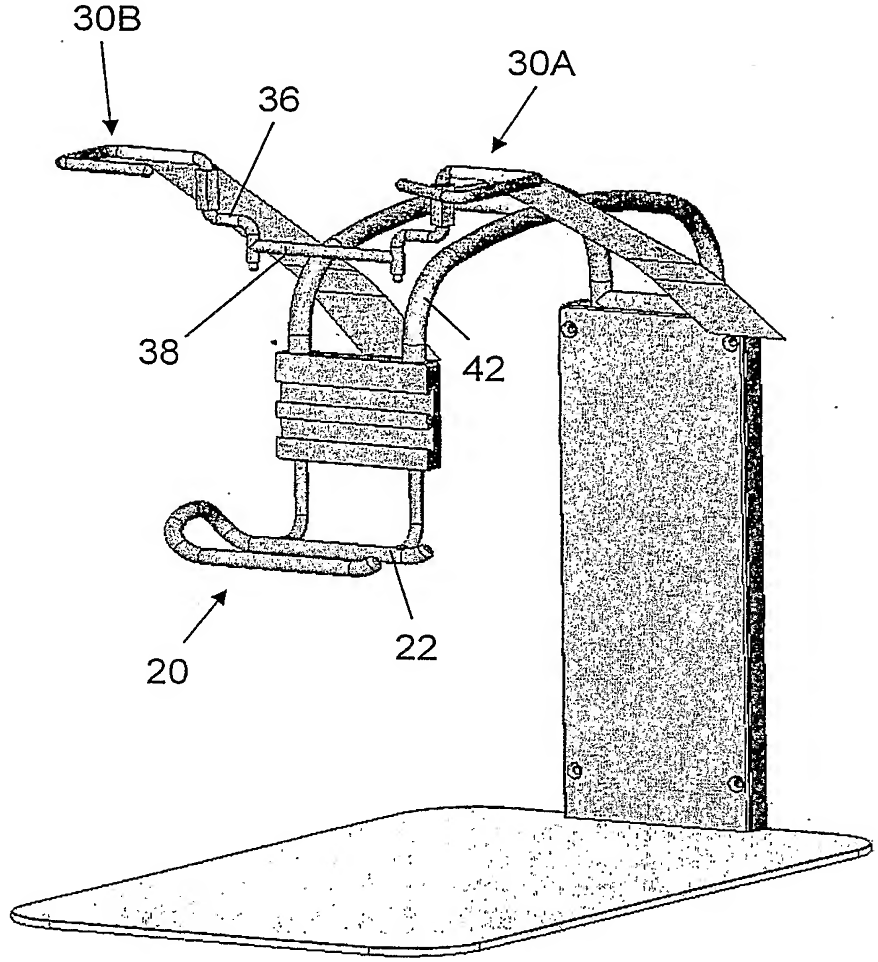

Fig. 4

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Nine Sheets of Drawings
Sheet No. 5

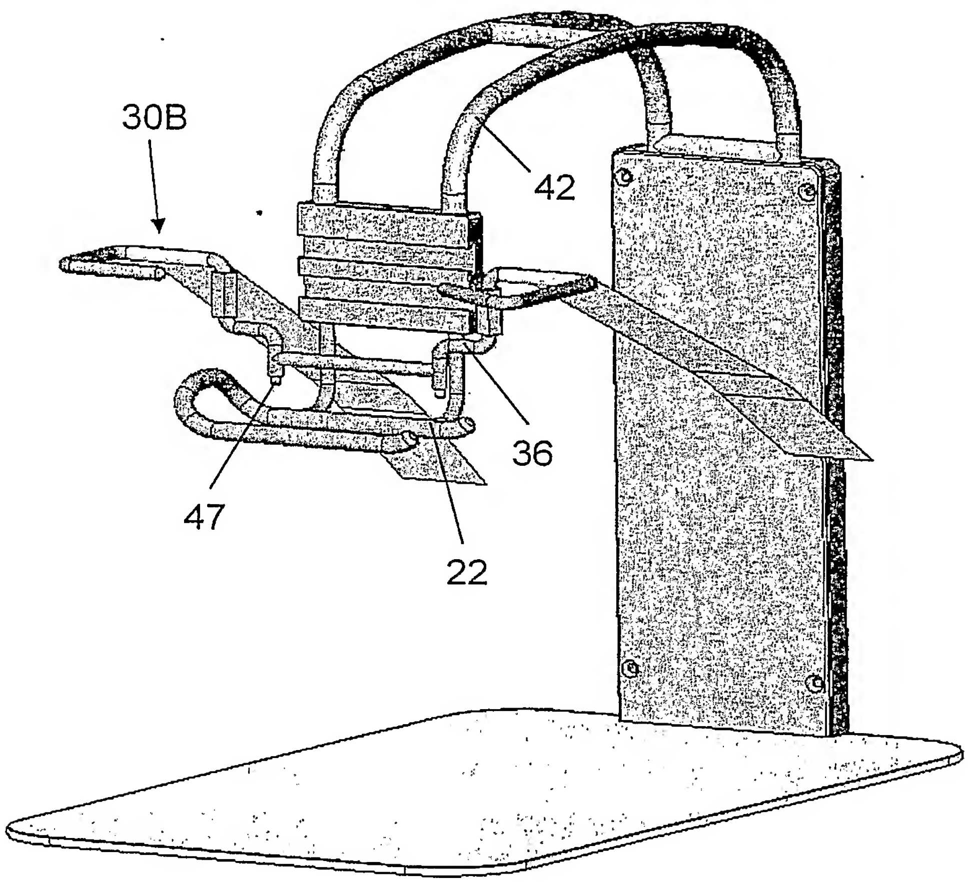

Fig. 5

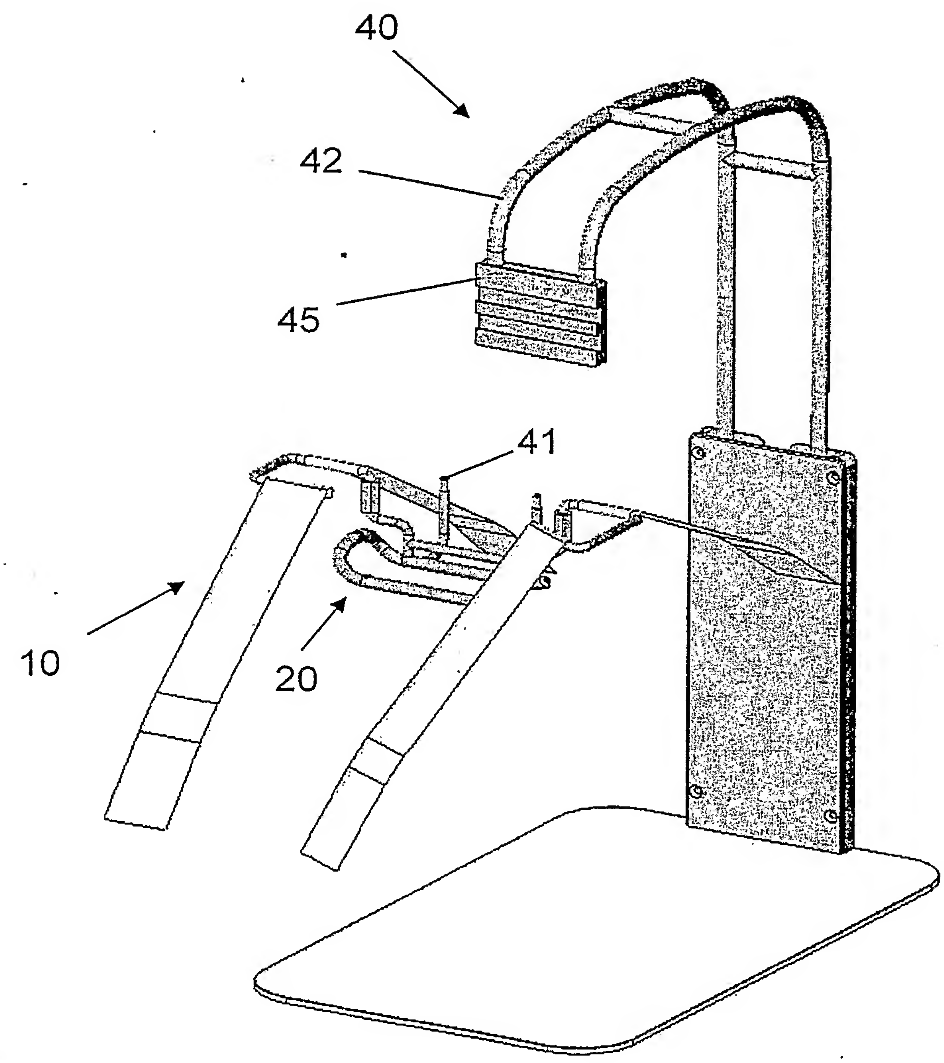

Fig. 6

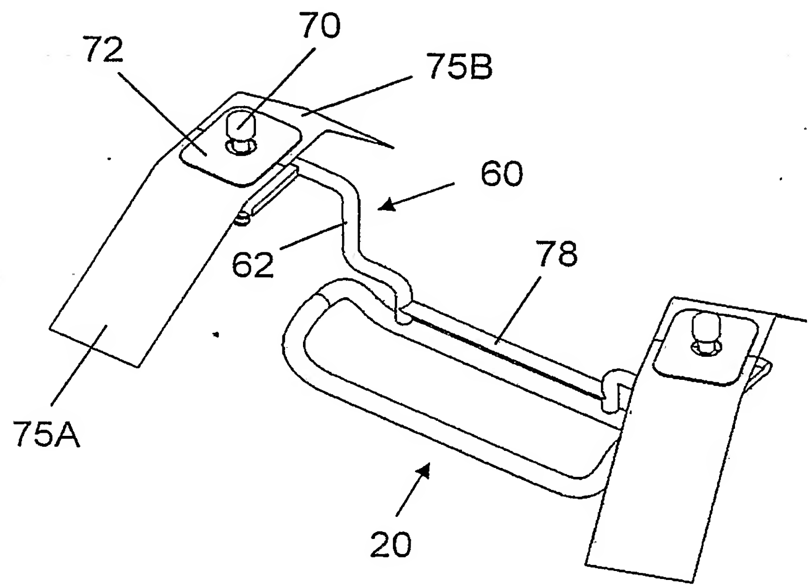

Fig. 7

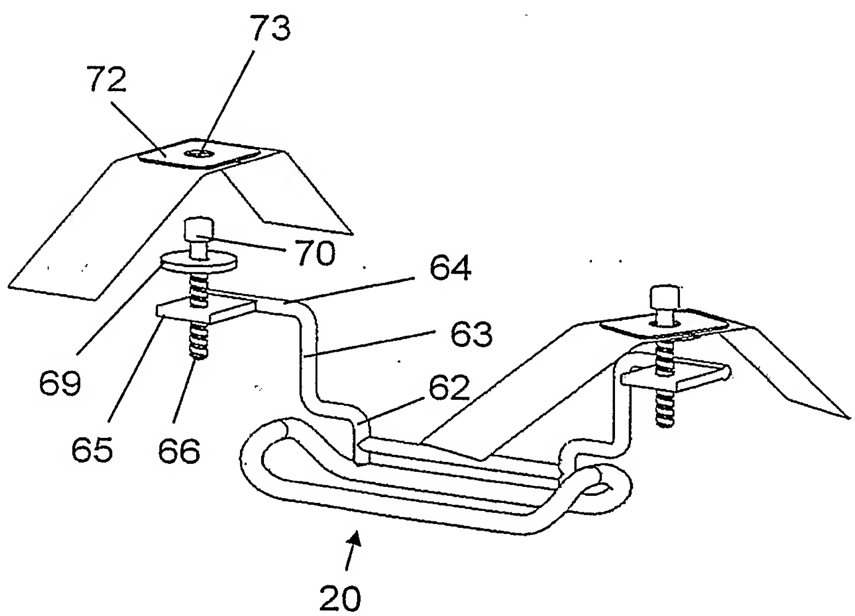

Fig. 8

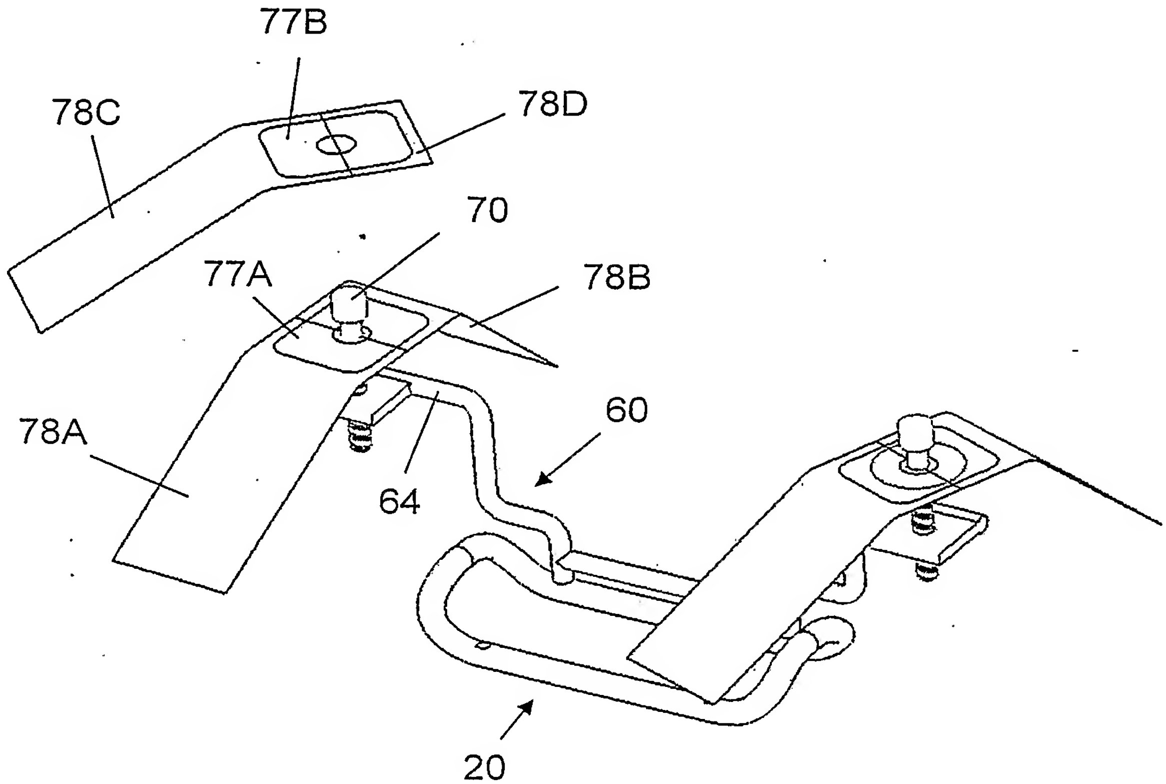

Fig. 9

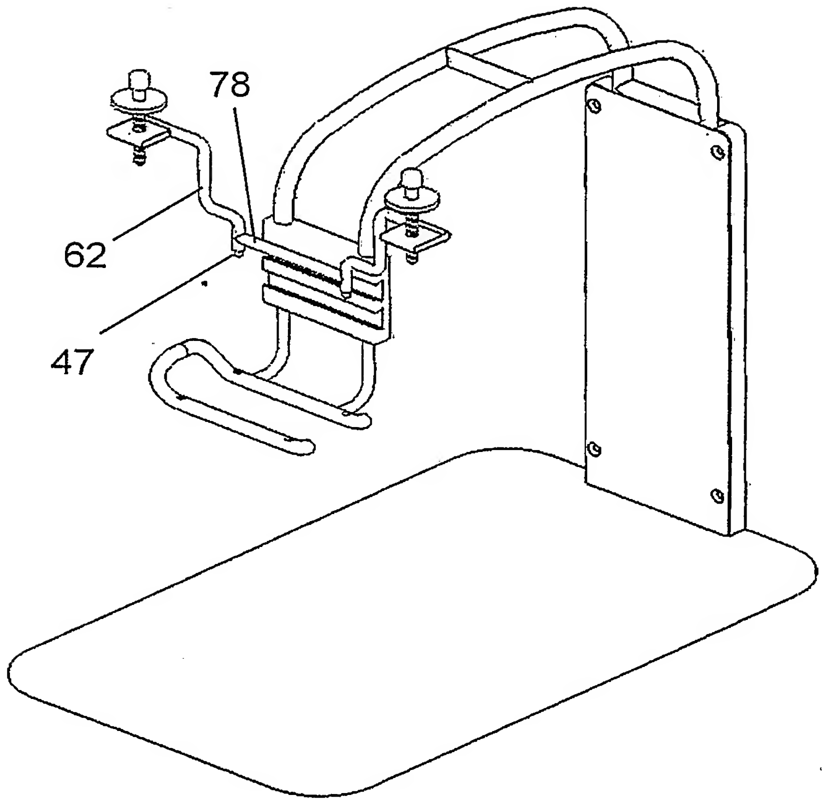

Fig. 10